Oath or Declaration

The Examiner has required that a new Oath or Declaration in compliance with 37 C.F.R. 1.67(a) be submitted. Applicants hereby submit a new Oath which identifies the applications to which applicants claim priority, thereby addressing this objection.

Double Patenting Rejection

The rejection of claims 1 and 3-7 under the judicially created doctrine of obviousness-type double patenting is traversed. Applicants respectfully request that the present double patenting rejection be held in abeyance until an indication of allowable subject matter, upon which indication a terminal disclaimer will be submitted.

Indefiniteness Rejection

The rejection of claims 1 and 8 under 35 U.S.C. § 112, second paragraph, as being indefinite is traversed and reconsideration is respectfully requested. Claim 1 has been amended to clarify how the delivery of a nucleotide sequence encoding p21 would inhibit alopecia, by defining that the expression of such nucleotide sequence would provide p21 to the hair follicle cells. In addition claim 8 has been amended to include a step of observing the fluorescence. As such, withdrawal of this rejection is respectfully requested.

Enablement Rejection

The rejection of claims 1-11 under 35 U.S.C. § 112, first paragraph, for not being supported in the specification so as to enable any person skilled in the art to make and/or use the invention commensurate in scope with the claims is traversed and reconsideration is respectfully requested.

The Examiner indicates that claims 1-11 are enabled for a method to inhibit chemotherapy induced alopecia by the topical administration of an effective amount of a nucleotide sequence encoding the p21 protein which upon expression would provide p21 to the

hair follicle cells of a mammal. Claim 1 has been amended to reflect the scope of what the Examiner indicates is enabled.

In addition, the Examiner indicates that the specification is enabling for a method of observing the *in vitro* expression of p21 hair follicles in cells on a histoculture by providing cells with an expression system contained in plasmid pEGFP-21. Claim 8 has been amended to reflect that the *in vitro* expression of p21 hair follicles in cells on a histoculture can be observed.

Further, the Examiner alleges that the specification enables only a method using an expression system that is plasmid pEGFP-21. It is respectfully submitted that there is no reason why other nucleotide sequences that encode an amino acid sequence that confers fluorescence other than pEGFP-21, which is included in Example 3 as a working example, would not work. Without a reason to doubt the objective truth of the statements made in the application, the application must be considered enabling with respect to claim 8. Please see *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971) and the Enablement Training Materials. Such reason to doubt the objective truth of the statements made in the application was not given, and thus a *prima facie* case of enablement has not been established.

Further, with respect to claim 8, the Examiner asserts that the specification enables only an *in vitro* method. However, it is respectfully submitted that an *in vitro* method is enabling for an *in vivo* method if there is a correlation with the working example. It is respectfully submitted that the *in vitro* working example relating to mice is sufficiently correlated to the claimed method of the invention. Specifically, the present specification on page 3, last paragraph, indicates that "an *in vitro* model for studying the anagen phase of the murine hair cycle for almost the entire duration has been developed." The Examiner has not given any reasons for a conclusion of lack of correlation for an *in vitro* animal model example. The Examiner alleges that the routes of administration, the frequency, and the dosage *in vivo* must be present but it is respectfully submitted that such information is not needed for a disclosure to be enabling for the present claims. Therefore, it is respectfully submitted that a *prima facie* case of enablement has not been established and, furthermore, that claim 8 is properly enabled.

In addition, the Examiner alleges that undue experimentation is required to determine which viral vector linked to which specific control sequence would be most suitable for the delivery of p21 to hair follicles. The Examiner cites Anderson in support of such argument, but it is respectfully submitted that Anderson suggests that such experimentation to determine which viral vector linked to which specific control sequence would be merely routine experimentation. Absolute predictability is not required for proper enablement. Thus, it is respectfully submitted that the dependent claims 2-4 are enabled by the present specification.

The Examiner also alleges lack of enablement with respect to a specific lipid or lipid formulation. Anderson is cited again by the Examiner to show lack of an enabling disclosure of a specific control or regulatory sequences. It is respectfully submitted that Anderson suggests that such experimentation is well within the skill of a skilled artisan and that such experimentation is routine. As absolute predictability is not required for enablement, it is respectfully submitted that claim 7 is properly enabled by the present specification.

The Examiner alleges that the specification is not enabling as it fails to teach the pharmaceutically acceptable composition or carrier of the topical agent to be applied to the skin. It is respectfully submitted that the present specification need not teach that which is well known. In addition, routine experimentation to determine the optimal formulation is respectfully submitted not to be undue experimentation.

The Examiner cites the Jimenez patent which discloses the treatment of alopecia with EGF and vitamin D3. However, the present claims are not directed to a treatment method using EGF and vitamin D3 so it is unclear why the present methods of the invention would be unpredictable, as the Jimenez patent does not suggest what the applicants are claiming. The present disclosure indicates that the methods work and this is demonstrated by the working example and the disclosure. The objective truth of the present disclosure is enabling unless a reason to doubt the truth of what is disclosed is given. It is respectfully submitted that a reference to different treatment method is not sufficient to show that the present treatment method lacks enablement, and thus *prima facie* enablement has not been established.

Therefore, it is respectfully submitted that the present claims are enabled by the present disclosure. Withdrawal of this rejection is respectfully requested.

Anticipation Rejection

The rejection of claims 1-7 under 35 U.S.C. § 102(e) as being anticipated by Lishko *et al.* (U.S. Patent No. 5,753,263) is traversed and reconsideration is respectfully requested.

Applicants respectfully request that the present rejection be held in abeyance until the indication of allowable subject matter, upon which indication, inventorship will be investigated.

On page 13 of the Office action, the Examiner indicated that "Claims 1-7 are directed to the same invention as that of claims 1-3, 8, 10, 13, 14, and 19 of commonly assigned US Patent No. 5,753,263. The issue of priority under 35 U.S.C. § 102(g) and possibly 35 U.S.C. § 102(f) of this single invention must be resolved." It is not clear whether the Examiner is making a rejection relating to same invention double patenting. Nonetheless, it is respectfully submitted that the scope of the claims in the present application are different than that scope in the 5,753,263 patent. Therefore, a "same invention" rejection is not applicable to the present claims. Similarly, the Examiner has not made a rejection under either of these two subsections of § 102. This application has common assignees with the 5,753,263 patent and thus, § 102(g) is not applicable. In addition, § 102(f) issues will be considered upon applicants' investigation of inventorship.

CONCLUSION

A new Oath has been submitted. In addition, claim 1 has been amended as suggested by the Examiner to overcome the rejections under 35 U.S.C. § 112. Claim 8 has been amended as suggested in part by the Examiner but nonetheless is submitted to be properly enabled. A terminal disclaimer and a declaration will be submitted upon an indication of allowable subject matter. It is respectfully submitted that all claims contain allowable subject matter and such indication is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 312762001800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: December 6, 2000 By: _____

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